

MEMORANDUM
Texas Department of Human Services

TO: Long Term Care-Regulatory
Regional Directors and State Office Managers

FROM: Susan Syler, Acting Unit Director
Long Term Care-Regulatory Policy
State Office MC: W-519

SUBJECT: Regional Survey & Certification Letter #03-02

DATE: March 14, 2003

The attached RS&C Letter is being provided to you for information purposes and should be shared with all professional staff.

- RS&C Letter No. 03-02 - **Focus** Validation Surveys of Accredited Hospitals

If you have questions about this subject, please contact Dodjie B. Guioa with Centers for Medicare and Medicaid Services at (214) 767-6179 or e-mail him at Dguioa@cms.hhs.gov.

[signature on file]

Susan Syler

SS:cos

[Attachment](#)

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January 2, 2003

REGIONAL SURVEY AND CERTIFICATION LETTER NO. 03-02

TO: All State Survey Agencies (Action)
All title XIX Single State Agencies (Information)

SUBJECT: Focus Validation Surveys of Accredited Hospitals

This letter delineates the responsibilities in the focus validation survey of accredited hospitals. It provides guidance to State Survey Agencies (SSA) in performing focus validation surveys.

INTRODUCTION

Validation surveys are designed to provide the oversight of the accreditation organizations (AO) by CMS. The recently revised hospital validation program was developed to improve CMS' oversight of the AOs whose accredited provider and suppliers are deemed to meet Medicare Conditions of Participation (CoPs). The three survey types are (1) Concurrent/Observational, (2) Focused, and (3) the Traditional. This survey protocol is for the Focused Survey. The Concurrent/Observational validation survey process is covered in a separate protocol. The Traditional validation survey protocol is documented in the State Operations Manual (SOM). The purpose of this protocol is to delineate the responsibilities of CMS and the State Survey Agencies (SAs) in the Focused Survey Process.

This protocol applies to deemed status hospitals that have voluntarily elected to participate in Medicare through accreditation by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or the American Osteopathic Association (AOA). Hospitals accredited by the JCAHO or the AOA are deemed to meet the requirements for participation in Medicare.

Focused surveys are designed to 1) provide insight into the ability of the hospital to maintain compliance with hospital standards by reviewing selected CoPs referred to as area(s) of focus, and 2) evaluate the effectiveness of the AO's accreditation requirements and monitoring. The focused survey is similar to the complaint survey conducted by the SAs. The major difference is that the focus of the survey will be determined by CMS based on its priorities for the year, patterns of deficiencies, and AO performance measures.



I. SELECTION OF AREAS OF FOCUS

Selection of CoPs to be surveyed will consider prevalence and severity of identified issues or problems. This protocol will be used to assess one or more national focus areas or Medicare Conditions of Participation (CoP) specified by CO (with RO and AO input). Selection criteria for areas of focus include the following:

- Patterns of deficiencies detected on hospital surveys;
- SA/RO/AO performance improvement initiatives;
- National trends as it relates to medical errors;
- Research priorities.

II. HOSPITAL SELECTION

In accordance with 42 CFR §488.7, an accredited hospital must participate in the hospital validation program, and therefore may be selected for a hospital validation survey. CMS Central Office (CO) will identify national criteria each year for selecting the hospitals that will have focused surveys as part of the hospital validation program.

Some examples of hospital selection criteria are:

- Size of the hospital;
- Location of the hospital;
- Patterns of deficiencies or complaint;
- History of hospital performance;
- National studies relating to improving medical care.

CO is responsible for identifying the number of validation surveys to be performed in each region. This information will be sent to all ROs before the start of each FY. The RO will select the requisite number of surveys using the specified criteria to create a representative sample of hospitals in the region, and each State when possible.

III. SURVEY SCHEDULING

Once the hospitals are selected for focused surveys, the RO initiates the scheduling process. The RO will:

- Prepare a Request for Validation of Accreditation Survey, Form CMS 2802 (see Exhibit 33) by:
 - ✓ Checking Item 5 indicating that **the facility is not to be notified more than 24 hours in advance (i.e., one-working day) prior to the start of the survey;**
 - ✓ Identifying the Medicare CoPs to be assessed in Item 7 of Form

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- ✓ CMS 2802 (e.g. areas of focus);
- ✓ Forwarding the completed CMS Form 2802 to the SA;
- Prepare facility notification letter (refer to Model 37C letter attached);
- Provide CO with 1) written notice of facility selections, 2) survey dates, and 3) copies of all correspondence to the facility (e.g. notification letters, plans of correction, 2567's);
- Inform CO of any changes to survey plans as soon as possible.

After receiving the CMS Form 2802, the SA will:

- Date-stamp the CMS 2802 form with the date of receipt;
- Schedule a survey between 60 days and 6 months following the AO accreditation survey and before the end of the fiscal year.

IV. PRE-SURVEY PREPARATION

SA follows the procedures given in the SOM at section 3244 for coordinating the focused survey as follows:

- Initiates the survey after receiving the request for Validation of Accreditation Survey, Form CMS 2802;
- Conducts the focused survey between 60 Days and 6 months following the AO accreditation survey and before the end of the fiscal year;
- Notifies the RO of the scheduled survey dates as soon as possible;
- **Provides the hospital with 24 hours notice prior to the start of the survey** (refer to Model 37C letter attached).

Once the SA schedule is confirmed with the RO, cancellation due to factors such as hospitals withdrawing from the accreditation process, and facilities closing will be accommodated. The SA will notify CMS RO as soon as these situations arise. The CMS RO in turn will notify the CMS central office. A replacement hospital will then be selected by the RO for the SA to survey. In the event the SA is not able to perform the survey within the acceptable range, the SA should immediately notify the RO, who in turn should notify the CMS central office. A collaborative decision between the RO and the SA will be made to determine if another time is acceptable to survey that facility or if the RO is to select another hospital which meets the national selection criteria from the list of deemed hospitals in the State. This decision should be made within 14 days of the SA notifying the RO, and the RO notifying the CO.

V. FOCUSED SURVEY PROCESS

The survey process is designed to evaluate the premise that a hospital that receives JCAHO or AOA accreditation is, in fact, meeting Medicare health and safety requirements. The SA conducts validation surveys of accredited hospitals in accordance with established procedures

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(SOM §3244, §3264) to ensure a fair basis for evaluating the effectiveness of approved accreditation organizations. The SA follows the procedures for conducting the focused survey as follows:

- Focused validation surveys are conducted between 60 days and 6 months following the AO Accreditation survey and before the end of the fiscal year;
- **The hospital is provided 24 hours notice** (refer to Model 37C letter attached);
- SA assigns surveyors who normally conduct surveys of nonaccredited hospitals. The SA may request assistance from the RO if it is unable to conduct the investigation within the 60-day time frame;
- If a hospital refuses to permit a focused validation survey, the SA follows the procedures in the SOM §3248;
- At the beginning of the focused survey the SA requests that the administrator complete the appropriate Request for Certification (Form CMS 1514 for hospitals);
- The SA conducts the focused survey in accordance with the survey protocol for hospitals, irrespective of the most recent survey date (e.g. a complaint survey conducted last month on Nursing Services CoP should not influence conducting a complete survey of Nursing Services CoP during this survey);
- SA only surveys the CoPs related to the area(s) of focus specified in the CMS 2802. A full and complete survey may be conducted if a CoP under focus is found out of compliance;
- SA uses the appropriate survey forms noted on the List of Documents in the Certification Packet (See Exhibit 35) and the interpretative guidelines when performing the survey.

VI. SA ACTIONS FOLLOWING FOCUSED SURVEY

Accredited Hospital Found In Compliance with Medicare CoPs Following Focused Survey

If the SA does not find a condition level deficiency, in accordance with the SOM § 3268, it completes a CMS 2567 consistent with the Principles of Documentation and concludes the inspection promptly with an exit interview. At the exit conference, the SA informs the hospital of the following:

- Standard level deficiencies detected;
- The SA will be completing a CMS 2567 noting the compliance status of the hospital;
- Form CMS 2567 will be forwarded to the RO within 10 days;
- RO will review the CMS 2567, consider the SA recommendation and make a decision on whether the facility is in compliance with Medicare

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CoPs;

- RO will provide the hospital with a decision letter and completed CMS 2567;
- Form CMS 2567 will be made available to the public under the disclosure of survey information provisions;
- The hospital may choose to offer a Plan of Correction (POC) for any standard level deficiencies cited and/or may refute the findings with evidence of how the deficiencies are in error.

Accredited Hospital Found Not In Compliance with Medicare CoPs Following Focused Survey

If the SA does find a condition level deficiency during the survey, it will proceed according to the SOM § 3270 as follows:

- Contact the RO and discuss the incidence and prevalence of its findings;
- If the RO determines that a condition level deficiency is probable, the RO will decide, in consultation with the SA, if the team should stay to perform a full survey or establish a target date for a full survey as soon as possible;
- If the decision is made to extend the focused survey to a full survey by the SA team on-site, the RO will advise the hospital and the AO that the hospital appears to be out of compliance with the Medicare CoPs and it will be placed under state monitoring until it is determined to be in compliance;
- SA conducts an exit conference. At the exit conference, the SA informs the hospital of the following:
 - ✓ Medicare CoPs found not in compliance;
 - ✓ Standard level deficiencies detected;
 - ✓ The SA will be completing a CMS 2567 noting the compliance status of the hospital;
 - ✓ Form CMS 2567 will be forwarded to the RO within 10 days;
 - ✓ RO will review the CMS 2567, consider the SA recommendation and make a decision on whether the hospital complies with Medicare CoPs;
 - ✓ RO will provide the hospital with a decision letter and completed CMS 2567;
 - ✓ Form CMS 2567 will be made available to the public under the disclosure of survey information provisions;
 - ✓ The hospital is subject to SA monitoring and must provide a Plan of Correction and evidence that it is in compliance with the requirements.

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The SA will submit the appropriate information as specified in Exhibit 63 to the RO or through an update to the OSCAR database within 30 days of completing the survey. The RO will then include this information in its notification to the AO about the survey results and request that the AO monitor the correction of the deficiencies.

Immediate Jeopardy Found during Focused Survey

If the deficiencies pose an immediate jeopardy, the hospital is subject to termination (See SOM §3010 and §3274) and the SA should proceed as follows:

- Immediately provide verbal notification to the hospital of its findings;
- Prepare a form CMS 2567 (SA is not to serve CMS 2567 to hospital on-site);
- Notify the RO for immediate action;
- Forward completed form CMS 2567 and other pertinent documents (see SOM §3010) to the RO within two days following the finding of an immediate jeopardy situation.

If the hospital has taken action and effectively abated the jeopardy prior to the SA exit, the SA will apprise the RO and subsequent actions will follow the standard procedures of the SOM § 3270 for adverse action. In addition, the SA must submit all the appropriate information specified in Exhibit 63 to the RO within two days of completing the survey. The SA prepares Form CMS 670, Survey Team Composition and Workload Report.

VII. RO ACTIONS FOLLOWING FOCUSED SURVEY

Upon receipt of survey materials, in accordance with SOM §3254, the RO reviews the CMS 2567, considers the SA recommendation and makes a decision on whether the facility meets Medicare CoPs. The RO takes necessary action within 30 days and inputs the information into OSCAR within 60 days of the compliance decision date.

If the RO determines that the accredited hospital is in compliance with all Medicare CoPs, it officially notifies the hospital (SOM Exhibit 194) and forwards a copy of the letter to the SA, CO and the AO. The notification letter advises that the AO may contact the hospital about the correction of any deficiencies below the Condition-level. The SA does not conduct follow-up visits.

If there are deficiencies at the Condition level the RO officially notifies the hospital (Exhibit 195) and forwards a copy of the letter to the SA, CO and the AO. This will remove the hospital from deemed status and place them under SA monitoring;

If there are deficiencies that pose an immediate jeopardy to patient health and safety, the provider or supplier may be subject to termination by the RO. (See SOM §§3010 and 3274.) The SA, CO and AO must be kept informed of the decisions made by the RO.

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Should the immediate jeopardy situation be corrected before the adverse action is taken or completed, the letter advises the hospital that the SA will conduct a revisit to inspect all remaining Conditions. When the hospital is cleared of all Condition-level deficiencies, the RO notifies the SA and the AO that the facility is being returned to deemed status.

Contact Dodjie B. Guioa by telephone at 214-767-6179 or through e-mail at Dguioa@cms.hhs.gov if you have any question with the foregoing matter.

Sincerely yours,

Molly Crawshaw, Chief
Survey and Certification Operations Branch

Attachment
SOM Exhibit 37C
Model Letter Announcing FOCUSED VALIDATION SURVEY

Hospital Name
Address

Provider Number:

Dear Administrator:

Section 1865 of the Social Security Act (the Act) provides hospitals accredited by the Joint Commission on Accreditation of Healthcare Organizations are deemed to meet the Medicare Conditions of Participation (CoPs) with the exception of those relating to utilization review and special psychiatric hospital staffing and medical records requirements. The law extends deemed status to hospitals accredited by the American Osteopathic Association with periodic review by the Secretary of Health and Human Services.

Section 1864 of the Act authorizes the Secretary to conduct on a selective sample basis, surveys of accredited hospitals as a means of validating the accrediting organization's survey requirements. In **(Name of State)**, Medicare sample validation surveys of accredited hospitals are conducted by the **(Name of State Survey Agency)**. This agency under agreement with the Centers for Medicare & Medicaid Services (CMS), formerly known as the Health Care Financing Administration, surveys hospitals and other providers of Medicare services to determine whether they meet the Medicare Conditions of Participation.

The last accreditation survey of **(Name of Hospital)** conducted by **(accrediting organization)** was completed on **(date)**.

We have scheduled a Medicare validation survey of your hospital to begin on **(date)**.

Section 1865 of the Act requires a hospital selected for a sample validation survey to authorize the accrediting organization to release to the Secretary (or to a State Survey Agency designated by him), upon his request, a copy of the most current accreditation survey of such institution. Your signature on Form CMS-1514 will authorize the accrediting organization to release its survey findings to CMS.

A copy of the Medicare sample validation survey findings will be subject to public disclosure after hospital staff have been given an opportunity to review the findings, present comments to us, and submit a plan of correction of deficiencies. The current accreditation survey report, however, is not disclosable to the public by CMS.

During this survey, the State Survey Agency will conduct a focused survey designed to target specific Conditions of Participation. If the Conditions under focus are determined to be out of

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compliance, a full survey of all Medicare CoPs may be conducted at this time. The survey team onsite may request any pertinent documentation needed for review. A representative from the CMS Regional Office may be in attendance on the survey.

If you have any questions regarding this letter, please contact **(Name)** at **(telephone number)**.

Sincerely yours,

State Survey Agency Director

Enclosures: Forms CMS-1513/CMS-1514

Cc: CMS/DSO/Regional Office
CMS/CMSO/Central Office